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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,532	09/04/2003	Balbir S. Brar	SABRA.001CP1	5571

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EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/655,532

Applicant(s)

BRAR ET AL

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/1/04; 2/6/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 7-11, 13, 15, 19-23, 25-29, 33-37, 39-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Falotico et al. 2003/0060877. Falotico et al. discloses the invention as claimed noting figures 27-28 comprising: A tubular stent with a proximal end, distal end and center portion; a first drug layer (1002), a second drug layer (1004), a third drug layer (1006) and a fourth drug layer (1008); and a polymer barrier layer between each of the layers (see sections [0203-0204]; wherein the first drug is Corticosteroid or where in the third drug is Paclitaxel or wherein the third drug is Taxol (this is inherent because Falotico et al. states that the drugs can be used in *any* layer or combination) It is inherent that a fifth and sixth layer can be incorporated as stated in section [0205].; wherein the first drug consist of Indomethacin ; Cisplatin; [0070] ; wherein the polymer can be biodegradable [ 0201]; wherein the proximal end and the distal end diameter are greater than the diameter of the center portion (see

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figure 12); wherein the stent is balloon or self-expandable [0201]; wherein the drugs are time released [[0200].

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-6, 14, 16-18, 24, 30-32, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. in view of Wnendt et al. 2004/0117008. Falotico et al. has been disclosed above however Falotico et al. does not disclose the drug Dexamethasone. Wnendt et al. teaches a stent with drug delivery properties that utilizes the drug Dexamethasone (see [0069]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the stent of Falotico et al. and utilize the drug Dexamethasone because it would be another drug that would provide immunosuppressants or antibiotic and is a matter of design choice.

5. Claims 12 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falotico et al. in view of Palasis et al. 6,369,039. Falotico et al. has been disclosed above however Falotico et al. does not disclose Polybutylene as one of the polymers.

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Palasis et al. teaches a drug delivery stent that utilizes Polybutylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Polybutylene as one of the polymers because it is a well know polymer in the use of tubular implants.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6,753,071; Rush 2004/0148010 ; Litvack et al. 2004/0143322 ; Davila et al. 2002/0111590 ; Lentz et al. 2002/0133183 ; Shulze et al. 2003/0088307 ; Chen et al. 2003/0108588 all show related material
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.
8. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

0858



Suzette J. Jackson

06 August 2004